UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PFIZER INC., PHARMACIA CORP., PHARMACIA & UPJOHN INC., PHARMACIA& UPJOHN COMPANY, G.D. SEARLE & CO, G.D. SEARLE LLC, SEARLE LLC (DELAWARE) and SEARLE LLC (NEVADA) Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	CIV. ACTION NO. 04-754 (JCL) **OPINION** Teva's In Limine Motion No. 6

LIFLAND, District Judge

INTRODUCTION

This case arises out of Teva Pharmaceuticals U.S.A., Inc.'s ("Teva" or "Defendant") alleged infringement of U.S. Patent Nos. 5,466,823; 5,563,165; and 5,760,068 (the "patents-in-suit"), which are held by Pfizer, Inc., Pharmacia Corp., Pharmacia & Upjohn Inc., Pharmacia & Upjohn Company, G.D. Searle & Co., G.D. Searle LLC, Searle LLC (Delaware), and Searle LLC (Nevada) (collectively "Pfizer" or "Plaintiffs"). The patents-in-suit are directed toward celecoxib, the active ingredient in Celebrex, and a broad genus of compounds that includes

celecoxib, pharmaceutical compositions including such compounds, and methods of using such compounds.

Before the Court is Teva's omnibus in limine motion No. 6 to preclude testimonial evidence regarding secondary considerations. Teva seeks to preclude Pfizer from offering testimony from the following experts regarding the indicated subject matter:

(A) Dr. William Galbraith — failure of other companies;

(B) Dr. Henry Grabowski — licensing and formulary acceptance;

(C) Dr. Randall Zusman — superior cardiovascular safety profile;

(D) Dr. Wang — endoscopic studies and overall safety; and

(E) Dr. Iannini — endoscopic studies and overall safety.

Under Federal Rule of Evidence 702, a court may allow an expert to give testimony that would otherwise be inadmissible

> [i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, [and] if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

F.R.E. 702. The Third Circuit has "explained that Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." Schneider v.

Fried, 320 F.3d 396, 404 (3d Cir. 2003).

> Qualification refers to the requirement that the witness possess specialized expertise. . . . Secondly, the testimony must be reliable; it "must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief. . . . Finally, Rule 702 requires that the expert testimony must fit the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact.

Id. (internal citations omitted). Teva contends, *inter alia*, that the indicated testimony of the five expert witnesses listed above fails to meet this trilogy of requirements.

A. Dr. Galbraith

Pfizer has indicated that it intends to offer testimony from Dr. Galbraith regarding the failure of others to achieve the claimed invention.[1] Specifically, Pfizer intends to elicit testimony from Dr. Galbraith regarding the failure of 27 other pharmaceutical companies to bring a COX-2 selective drug to market in the United States. Teva argues that this testimony should be precluded because it fails to satisfy the second and third requirements of Rule 702—reliability and fit.

First, Teva argues that Dr. Galbraith used the "wrong metric or benchmark

[1] It is well established that the failure of others to develop alternatives to the invention may be evidence of non-obviousness. Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966).

to assess 'failure of others.'" (Memorandum in Support of Teva's Omnibus in Limine Motion No. 6, at 4.) The benchmark he used was whether any company, which had a COX-2 selective compound in preclinical and clinical testing, succeeded in obtaining Food and Drug Administration ("FDA") approval for a product and bringing it to market in the United States. In Knoll Pharm. Co. v. Teva Pharms. USA, Inc., the Federal Ciruit endorsed (albeit indirectly) the use of this benchmark. 367 F.3d 1381, 1385 (Fed. Cir. 2004). In Knoll, a patent holder offered evidence of the failure of two pharmaceutical companies to obtain FDA approval for codeine-naproxen sodium and codeine-ibuprofen combinations. The district court found that this evidence was insufficient to support a finding of failure by others—not because the expert used the incorrect benchmark, but because there were other opioid-NSAID compositions available on the market. The Federal Circuit reversed. Id. Given this implicit acceptance of failure to obtain FDA approval as an appropriate benchmark in evaluating failure of others, this Court finds that Dr. Galbraith's use of this benchmark was not error warranting preclusion of his testimony.

The use of this "benchmark" was appropriate methodology and resulted in reliable evidence. In deciding how to approach the issue of failure of others to solve the problem which the patented invention solved, it is appropriate

methodology to first state the problem: "The problem to be solved here was that prior art NSAIDs were associated with gastrointestinal side effects that limited their therapeutic potential." (Plaintiffs' Opposition to Teva's Omnibus in Limine Motion No. 6, at 3.) Next, in view of the undisputed unmet need for a solution to that problem, Dr. Galbraith turned to the failed efforts of many other companies. Teva's argument that "[a] 'failure of others' analysis should address whether other companies failed to solve the problem solved by the invention, not whether anyone succeeded in obtaining FDA approval in the U.S. so that they could market their product in the U.S." ignores the fact that getting to market after securing FDA approval is the inevitable corollary of solving the problem where there is an unmet need. Therefore, not getting to market with FDA approval is an appropriate benchmark for failure.

Next, Teva argues that Dr. Galbraith ignored factors—unrelated to whether the company was technologically successful at solving the problem—that can influence whether a company takes a product to market. At deposition, Dr. Galbraith admitted that there are hypothetical reasons other than technological failure—including business reasons, a change in the focus of the company, or the existence of a blocking patent—that could influence why a company failed to bring a COX-2 selective compound to the market. (Declaration of Michael E.

Petunas in Support of Teva's Motion in Limine No. 6 (hereinafter, "Patunas Decl."), Ex. C, at 116:15-117:22, 118:14-17.) Teva contends that Dr. Galbraith's failure to consider these other possible factors with respect to each of the companies renders his opinions inadmissible. Pfizer responds to this assertion by arguing that Dr. Galbraith did in fact consider business reasons, and "did opine on why several companies, including DuPont Merck, Merck, and Novartis failed to bring their lead compounds to market." (Plaintiffs' Opposition to Teva's Omnibus in Limine Motion No. 6, at 4.)

Although an expert "must consider enough factors to make his or her opinion sufficiently reliable in the eyes of the court . . . [the] expert need not consider every possible factor to render a 'reliable' opinion." MicroStrategy Inc. v. Business Objects, S.A., 429 F.3d 1344, 1355-1356 (Fed. Cir. 2005). Moreover, a district court is not required to preclude expert testimony simply because the proposed expert could have performed his or her analysis in a better manner. See Kannankeril v. Terminix Int'l, 128 F.3d 802, 809 (3d Cir. 1997). As the Third Circuit has stated:

> A judge should find an expert opinion reliable under Rule 702 if it is based on "good grounds," i.e., if it is based on the methods and procedures of science. . . . The grounds for the expert's opinion merely have to be good, they do not have to be perfect. The judge might think that there are good grounds for an expert's conclusion

> even if the judge thinks . . . that a scientist's methodology has some flaws such that if they had been corrected, the scientist would have reached a different result.

In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 745 (3d Cir. 1994). Under this standard, the Court finds Dr. Galbraith's expert testimony to be sufficiently reliable, particularly when he referred to several concrete instances of technological failure, unrelated to "business" reasons.

Teva's concern with the comprehensiveness of Dr. Galbraith's methods "goes more to the weight of the evidence than to its admissibility." Liquid Dynamics Corp. v. Vaughan Co., 449 F.3d 1209, 1221 (Fed. Cir. 2006). As such, it is appropriately addressed in cross examination rather than in a motion in limine to preclude the evidence altogether. See In re TMI Litig., 193 F.3d 613, 692 (3d Cir. 1999) ("'So long as the expert's testimony rests upon "good grounds," it should be tested by the adversary process–competing expert testimony and active cross-examination– rather than excluded from jurors['] scrutiny . . . .'") (quoting Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co., 161 F.3d 77, 85 (1st Cir. 1998)); see also Daubert v. Merrell Dow Pharms., 509 U.S. 579, 596 (1993) ("[V]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). After hearing all of the evidence,

including Teva's evidence as to reasons for failure of others to bring a COX-2 selective compound to market, the Court will determine how much weight, if any, to accord to Dr. Galbraith's testimony.

Finally, with respect to Dr. Galbraith's proposed testimony, Teva argues that Dr. Galbraith "bases his opinion on documents that don't show failure and thereby attempts to prove a negative." (Memorandum in Support of Teva's Omnibus in Limine Motion No. 6, at 6.) The documents in question are industry publications—entitled "Trends and Perspectives, 'To Market, To Market'"—that list all of the compounds launched in a given year. (Patunas Decl., Exh. A, at 15 n.3.) The Court finds that it was proper and reasonable for Dr. Galbraith to rely on these lists as evidence that a company failed to achieve the claimed invention. The fact that a product does not appear on any of the lists is reliable evidence that the product was not launched.

Accordingly, Teva's motion to preclude Dr. Galbraith's testimony on the issue of failure of others will be denied.

B. Dr. Grabowski

Pfizer has indicated that it intends to offer the testimony of economist Henry

Grabowski in support of its claim that the licensing of celecoxib and deracoxib[2] is evidence of the non-obviousness of the patents-in-suit. The secondary consideration of the existence of licenses under the patented invention, may be "highly probative of the issue of nonobviousness." Arkie Lures, Inc. V. Advanced Semiconducter Materials Am., Inc., 98 F.3d 1563, 1570 (Fed. Cir. 1997).

Nonetheless, Teva objects to the proposed evidence on two grounds. First, Teva argues that Dr. Grabowski's testimony regarding the licensing of celecoxib is irrelevant. In February 1998, a year before Celebrex was launched, plaintiffs G.D. Searle (the patentee) and Pfizer Inc. (the licensee) entered into an agreement giving Pfizer Inc. "the exclusive right . . . to promote and detail" Celebrex in the United States (the "U.S. Collaboration Agreement (Celecoxib)").[3] (Declaration of Daniel Reisner in Support of Plaintiffs' Opposition to Teva's Motions in Limine Nos. 1-7 (hereinafter, "Reisner Decl."), Ex. 22, at § 2.1.) Teva does not dispute that the patents-in-suit were licensed to Pfizer in the U.S. Collaboration Agreement. (Memorandum in Support of Teva's Omnibus in Limine Motion No.

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[2] Deracoxib is the active ingredient is Deramaxx, an anti-inflammatory drug used for treatment of pain and arthritis in dogs. Several of the asserted claims of the patents-in-issue cover deracoxib and many other similar compounds in addition to celecoxib.

[3] The parties entered into a separate agreement covering rights outside the United States.

6, at 12.) However, Teva argues that Dr. Grabowski's analysis (1) focuses on the wrong question, and (2) fails to establish the required nexus between the licensing agreement and the merits of the claimed invention.

With respect to (1), Teva claims Dr. Grabowski incorrectly focused on "how much Pfizer was willing to spend to 'get access to the drug' to be commercially sold as Celebrex rather than how much Pfizer was spending for the license to the patents-in-suit." (Id. at 11.) The Court agrees with Pfizer that this is a distinction without a difference.

With respect to (2), Federal Circuit case law requires affirmative evidence of nexus. See, e.g., Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1324 (Fed. Cir. 2004); In re GPAC Inc., 57 F.3d 1573, 1580 (Fed. Cir. 1995); see also Roger Schechter and John Thomas, Principles of Patent Law 166 (2d ed.) ("In enforcing the nexus requirement, the courts will ensure that the competitors did not take a [license] . . . for other reasons that do not support the nonobviousness of the claimed invention."). However, the Court also notes that the Federal Circuit has not found that the lack of such nexus evidence warrants preclusion. In such cases, courts simply accord little weight to the licensing evidence; they do not preclude its admission altogether. See, e.g., Iron Grip Barbell Co., 392 F.3d at 1324; In re GPAC Inc., 57 F.3d at 1580.

Nevertheless, if the Court were convinced that there was no evidence of nexus, and that the licensing evidence was of no significance at all, it would consider precluding the testimony in order to conserve time and resources. However, such a conclusion would be premature at this point. The parties' arguments on the nexus requirement consist of only one paragraph each, and the evidence has yet to be developed in any meaningful way. If, at trial, Pfizer fails to show that the license arose out of recognition and acceptance of the claimed subject matter, the Court will, as required by the case law, accord the licensing evidence little or no weight.

Turning to Teva's arguments concerning Deramaxx, Teva essentially repeats the arguments set forth in Teva's in Limine Motion No. 5 to preclude evidence relating to Deramaxx. The Court will not repeat its analysis of the issue here. Instead, the Court incorporates the discussion from the Court's opinion in Teva's in Limine Motion No. 5. For the reasons stated in that opinion, Teva's motion to preclude Dr. Grabowski's testimony regarding the licensing of deracoxib will be denied.[4]

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[4] Teva also argues in its in limine motion No. 6 that any licensing of Deramaxx is irrelevant to asserted claims that do not encompass deracoxib. (Only compound claims 1-3, 7, and 8 of the '823 patent, and composition claims 1-4, 15, and 16 of the '165 patent cover deracoxib. (Memorandum in Support of Teva's Motion in Limine No. 5, at 4.)) Pfizer responds that "Plaintiffs have never

Finally, with respect to Dr. Grabowski's testimony, Teva argues that Dr. Grabowski's licensing opinions should be precluded in their entirety because he did not apply reliable principles and methods.[5] Contrary to Teva's assertion that Dr. Grabowski never disclosed any logic or methodology to support his conclusions, Dr. Grabowski explained during his deposition that he relied on an economic analysis of costs, risks, and return as well as his familiarity and experience with licensing agreements in the pharmaceutical industry. (See Reisner Decl., Ex. 45, at 192.) Accordingly, the Court finds Dr. Grabowski's testimony to be sufficiently reliable to pass muster under § 702. As with Dr. Galbraith's testimony, see supra Part A, Teva will be able to address its concerns about the reliability of Dr. Grabowski's testimony at trial through cross-examination and the presentation of contrary evidence.

Accordingly, Teva's motion to preclude Dr. Grabowski's testimony on the

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asserted that the Deramaxx license is evidence of the non-obviousness of all asserted claims." (Plaintiffs' Opposition to Teva's Omnibus in Limine Motion No. 6, at 9.) Accordingly, the Court will only consider the Deramaxx license, if at all, as evidence of non-obviousness with respect to the claims that encompass deracoxib.

[5] As explained above, expert testimony must be reliable, "it must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; [and] the expert must have good grounds for his on her belief." Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (internal quotations and citations omitted).

issue of licensing will be denied.[6]

C. Dr. Zusman

Dr. Zusman is an Associate Professor of Medicine at the Harvard Medical School and Director of the Division of Hypertension and Vascular Medicine in the Cardiac Unit of Massachusetts General Hospital. Pfizer intends to offer testimony from Dr. Zusman regarding the cardiovascular properties of Celebrex, Vioxx, and traditional non-selective NSAIDs. Specifically, Dr. Zusman plans to testify that Celebrex has a cardiovascular profile that is superior to Vioxx, and possesses unexpected cardiovascular properties compared to Vioxx and traditional non-selective NSAIDs. Teva objects to the proposed testimony on several grounds, namely that it is irrelevant, unreliable, and untimely.

As to the relevance of Dr. Zusman's proposed testimony, Pfizer asserts that Dr. Zusman's opinions are probative of (1) the commercial success of Celebrex

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[6] In the introduction to its motion papers, Teva states that Dr. Grabowski's testimony regarding "formulary acceptance" should be precluded. However, Teva does not present any arguments on this issue in its Memorandum. Accordingly, the Court will deny Teva's motion to preclude Dr. Galbraith's testimony on the issue of formulary acceptance. See Sanchez v. Miller, 792 F.2d 694, 703 (7th Cir. 1986) (explaining that "the court is not obligated to research and construct [a party's] legal arguments, especially since it is represented by counsel"); cf. Pennsylvania Dep't of Pub. Welfare v. United States HHS, 101 F.3d 939, 945 (3d Cir. 1996) (explaining that arguments mentioned in passing but not directly argued will be deemed waived).

and (2) the unexpected benefits of Celebrex over the prior art, both of which are secondary considerations that may rebut a *prima facie* showing of obviousness. See Graham, 383 U.S. at 17-18. Teva disputes that Dr. Zusman's testimony is relevant to either secondary consideration.

(1) Commercial Success

It is well established that an invention's commercial success constitutes strong evidence of non-obviousness. See, e.g., Demaco Corp. v. F. Von Langsdorff Licensing, Ltd., 851 F.2d 1387, 1391 (Fed. Cir. 1988). The rationale behind this secondary consideration is fairly simple: "In such circumstances the marketplace is presumed to have provided others with ample incentive to perfect the invention, and their failure to do so suggests nonobviousness." Roger Schechter and John Thomas, Principles of Patent Law 164. To be relevant, the commercial success must be due to a claimed feature of the invention, not to other factors such as marketing, superior workmanship, or other features within the commercialized technology. See, e.g., id. In addition, in the Court's view, the invention's commercial success must be due to a feature that was contemplated at the time of invention. If the commercial success results from a feature of the invention that was entirely unanticipated by the inventors or the field at large, the premise underlying the relevance of commercial success as indicative of non-

obviousness is destroyed; in such circumstances, the marketplace cannot be presumed to have provided others with any incentive to perfect the invention, and accordingly their failure to do so does not suggest non-obviousness. This is the situation presented here.

Pfizer intends to use Dr. Zusman's testimony to show that the commercial success of Celebrex was due to a claimed feature of the invention, namely its superior cardiovascular properties. But this feature was not contemplated at the time of invention. The patents-in-suit make no mention of such cardiovascular benefits. (Patunas Decl., Exhs. K, L, M.) Indeed, the cardiovascular risks associated with COX-2 inhibitors were not known at the time of Celebrex's invention. As explained by another Pfizer expert, Dr. Grabowski, concerns about the cardiovascular side-effects of COX-2 selective inhibitors did not arise until in or about 2001. (Id., Exh. N, at 22 & n.69.) Thus, there was no market demand for a COX-2 inhibitor with superior cardiovascular properties, and no corresponding incentive to create one. Thus, commercial success due to this feature does not suggest non-obviousness of the invention and is not relevant to the obviousness inquiry.

(2) Unexpected Results

Like commercial success, a showing that an invention exhibits superior and

unexpected properties can be indicative of non-obviousness. See, e.g., American Hoist & Derrick Co. v. Sowa & Sons, 725 F.2d 1350, 1360 (Fed. Cir. 1984). The reasoning behind this secondary consideration is straightforward:

"that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious." In re Mayne, 104 F.3d 1339, 1343 (Fed. Cir. 1997) (quoting In re Soni, 54 F.3d 746, 750 (Fed. Cir. 1995)). In other words, if the hypothetical person with ordinary skill would have been surprised that a particular combination of elements would achieve the desired result, it would probably not have been obvious to combine those elements to achieve that result.

Pfizer contends that Celebrex's superior cardiovascular properties constitute unexpected results that support a finding of non-obviousness. The Court disagrees. Although an unexpected result could not, by definition, have been anticipated at the time of invention, the Court holds that for an unexpected property of an invention to be evidence of non-obviousness it must have been contemplated as a goal of the inventive process. The fact that the hypothetical person of ordinary skill would have been surprised to learn that the particular combination of elements created an unexpected benefit completely unrelated to the desired outcome does not logically imply that it would not have been obvious to combine those elements to achieve the desired result.

This holding is supported by several cases that preclude reliance by an inventor or patentee on undisclosed, later-discovered advantages. In Tinnerman Products, Inc. v. George K. Garrett Co., for example, the United States Court of Appeals for the Third Circuit held that "where the particular feature relied upon is nowhere mentioned as an advantage, it cannot form the basis of patentability." 292 F.2d 137, 140 (3d Cir. 1961) (citing In re Berliner, 195 F.2d 918, 920, (C.C.P.A. 1952); In re Wright, 256 F.2d 583, 589 (C.C.P.A. 1958); In re Stewart, 222 F.2d 747, 754 (C.C.P.A. 1955)). See also, e.g., Carter-Wallace, Inc. v. Otte, 474 F.2d 529, 540 (2d Cir. 1972) ("[T]he novel, unexpected, or superior nonobvious property must be disclosed in the patent application or at least in supporting documents in order to be relied upon as a basis for patentability."); Struthers Patent Corp. v. Nestle Co., 558 F. Supp. 747, 808 (D.N.J. 1981) ("The applicable law is clear that where the particular feature relied upon is nowhere mentioned as an advantage it cannot form the basis of patentability.").

Here, the unexpected result—the alleged lack of cardiovascular side effects—was not contemplated as a goal of the inventive process. See supra Part C. The fact that a person of ordinary skill would have been surprised by the cardiovascular properties of Celebrex does not imply that it was not obvious to create this compound to produce an NSAID with reduced gastrointestinal side

effects. Thus, this unexpected result does not suggest non-obviousness of the invention and is not relevant to the obviousness inquiry.

Accordingly, Teva's motion to limit Dr. Zusman's trial testimony on the alleged superior cardiovascular safety profile and cardiovascular properties of Celebrex will be granted.[7]

D & E. Drs. Wang and Iannini

Dr. Wang is the Chief of Diagnostic and Liver Diseases at Columbia University Medical Center. Dr. Iannini is a practicing rheumatologist with twenty years of experience. Pfizer plans to offer expert testimony from both of these doctors concerning data evidencing the gastrointestinal safety of Celebrex over other NSAIDs, and the reasons why physicians prescribe Celebrex over other NSAIDs. Specifically, Drs. Wang and Iannini plan to testify, *inter alia*, about the results of numerous clinical studies evaluating the incidence of endoscopically-observed ulcers in patients taking Celebrex as compared to other traditional NSAIDs. Teva argues that evidence concerning these endoscopic studies should be precluded because it is not probative of the alleged superior gastrointestinal

[7] Because the Court is granting Teva's motion on the ground of irrelevance, the Court need not address Teva's alternative arguments that Dr. Zusman's opinions are unreliable and that his expert report was not timely submitted in accordance with the agreement of the parties.

safety of the compounds in the asserted claims, including celocoxib, and will not assist the Court in determining the obviousness of the asserted patent claims.

Pfizer contends that testimony regarding the endoscopic studies is relevant to demonstrating Celebrex's commercial success and that Celebrex resolved a long-felt need in the market. Teva does not dispute that evidence of superior gastrointestinal safety is relevant to these issues. Nor does Teva dispute, at this juncture, the experts' opinion that Celebrex is associated with a significant reduction in endoscopically-observed ulcers. Rather, Teva argues that evidence regarding the results of endoscopic studies will not assist the Court in deciding whether Celebrex in fact provides superior gastrointestinal safety as compared to other NSAIDs.

Endoscopic studies are clinical studies in which patients undergo a procedure called an "endoscopy," which involves insertion of a tube or scope carrying a small camera (an "endoscope") into the patient's gastrointestinal tract. This enables the physician to view the interior surfaces of the gastrointestinal tract and identify any lesions or irregularities, including so-called "endoscopic ulcers." Endoscopic ulcers are breaks in the mucosa of the stomach and intestine greater than 3 mm that extend into the submucosa. These ulcers are defined visually by endoscopy rather than by gastrointestinal symptoms such as pain.

Teva argues that these endoscopic ulcers are not on their own clinically important events, and that symptomatically defined ulcer complications (i.e., complicated ulcers and symptomatic ulcers) should define the gastrointestinal safety of an NSAID. In support of its argument, Teva relies heavily on the refusal of the Food and Drug Administration ("FDA") to allow Pfizer to make any claims on its package label for Celebrex regarding superiority in the rates of clinically significant gastrointestinal events based on the endoscopic data. Pfizer requested permission to include a statement on the Celebrex label that "[t]he incidence of upper GI ulcer complications for Celebrex was similar to placebo and showed an 8-fold reduction compared to NSAIDs." (See Patunas Decl., Ex. X, at 6.) In support of this requested labeling, Pfizer presented the FDA with the results of endoscopic studies that demonstrated a statistically significant lower incidence of gastric ulcers and lesions as compared to traditional NSAIDs. The FDA did not accept this evidence, noting that "the clinical significance of the lower rates of endoscopic ulcers associated with Celebrex has yet to be established." (Id., Ex. Z, at 121.)[8]

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[8] Teva asserts that the FDA examiner also stated that "'[t]here is no conclusive evidence that the occurrence of NSAID related ulcers will predict the risk of complicated ulcers.'" (Memorandum in Support of Teva's Omnibus in Limine Motion, No. 6, at 31.) The Court was unable to locate the source of this quotation.

In response, Pfizer points out that the FDA-approved label for Celebrex currently includes both endoscopic data as well as rates of complicated and symptomatic ulcers. (See Reisner Decl., Ex. 37, at 8-10.) Pfizer also argues that the incidence rate of endoscopically-observed ulcers is predictive of the incidence rate of complicated ulcers and a clinically meaningful measurement of gastrointestinal safety. In support of this argument, Pfizer cites, *inter alia*, deposition testimony of one of Teva's own witnesses, Dr. Wolfe:

> Q. What's your view on whether MUCOSA shows a correlation between endoscopic ulcer data and complicated ulcers.
> A. Not direct, because it wasn't the same study. But yes, it does show there is a correlation between the effect of endoscopic ulcers versus complicated ulcers.

(Id., Ex. 32 at 88.)

This evidence of a predictive relationship between endoscopically-observed ulcers and complicated ulcers supports a finding that Celebrex provides superior gastrointestinal safety, which in turn is relevant to the secondary consideration of commercial success. Therefore, the ultimate issue presented by Teva's argument is how much weight should be assigned to endoscopic ulcer data among other measurements of gastrointestinal impact, such as complicated ulcers, symptomatic ulcers, and gastrointestinal tolerability. As such, it is appropriately addressed in cross examination rather than in a motion in limine to preclude the evidence

altogether. See, e.g., In re TMI Litig., 193 F.3d at 692; Daubert v. Merrell Dow Pharms., 509 U.S. at 596 (1993). After hearing all of the evidence, the Court will determine how much weight, if any, to accord to the results of the endoscopic studies.

CONCLUSION

In summary, Teva's motion in limine No. 6 to preclude testimonial evidence regarding secondary considerations will be granted in part and denied in part. The Court will grant Teva's motion to limit Dr. Zusman's testimony concerning the cardiovascular properties of Celebrex compared to Vioxx and other traditional NSAIDs. The motion will be denied in all other respects.

/s/ John C. Lifland, U.S.D.J.

Dated: November 3, 2006